REMARKS

Claims 1, 8, 18, and 26 have been amended. Claims 1, 8, 18, and 26 have been amended to delete reference to SEQ ID NOs:1 and 2. Claim 1 has been amended to replace "85%" with "95%" and to refer to specific regions of SEQ ID NO:3. Support for this amendment is found throughout the specification as filed, e.g., in original claim 8, and page 2, lines 34-38. Claim 26 has been amended to refer to insert the phrase "consisting of the fully complementary sequence of" SEQ ID NO:3. This amendment is supported by claim 26 as originally filed. Claims 6 and 23 have been canceled.

A replacement Sequence Listing is enclosed herewith. The replacement Sequence Listing includes the polypeptide sequences depicted in the drawings filed with the application.

No new matter has been added by the present amendment. Upon entry of this amendment, claims 1, 6, 8, 15-18, and 26, will be pending and under examination.

Rejections under 35 U.S.C. § 101

Utility

Claims 1 (c), 6, 8 (g-i), 15-17, 18 (c), 23, and 26 (c) were rejected as lacking patentable utility. In the Office Action, it was alleged that

> [t]he polypeptide encoded by a nucleic acid comprising the nucleotide sequence of SEQ ID NO:3 lacks a specific utility…The instant specification is silent as to the function and proteolytic breakdown of polypeptides encoded by SEQ ID NO:3, having at least 85% identity to SEQ ID NO:3, or having at least 30-100 nucleotides from SEQ ID NO:3. Indeed, no polypeptides or polypeptides [sic] sequences are taught in the specification (page 3).

This is respectfully traversed. The claims, as amended, are drawn to various polypeptides, e.g., encoded by a nucleic acid molecule at least 95% identical to a polypeptide encoded by nucleotides 585-2156 of SEQ ID NO:3, nucleotides 2307-5741 of SEQ ID NO:3, or nucleotides 5620-7533 of SEQ ID NO:3; to polypeptides encoded by sequences at least 30 nucleotides in length from SEQ ID NO:3; and to polypeptides encoded by a sequence at least 100 nucleotides in length that hybridizes under stringent conditions to SEQ ID NO:3. Applicant

disagrees with the statement that "no polypeptides" or polypeptide sequences are taught in the specification. The specification discloses nucleotide sequences and describes regions of the sequences that encode retroviral polypeptides (e.g., gag, pol, and env polypeptides). The specification also discloses polypeptide sequences encoded by the nucleotide sequences. See, e.g., Figures 2 and 3.

Applicant maintains that the asserted utilities are specific. A utility is specific if it is specific to the subject matter claimed. Applicant has asserted utilities for the claimed polypeptides, for example, in methods of detecting porcine retroviruses and screening animals for retrovirus infection. See the specification, e.g., at page 24, lines 23-28, page 30, lines 25-27, and page 39, lines 13-20. A utility is general if it is applicable to the broad class of the invention. The asserted utilities do not apply to *any* polypeptide. These cannot be characterized as general, non-specific utilities. One cannot carry out methods for detecting swine retroviruses with any, non-specific polypeptide. Applicant has indicated that the claimed polypeptides are useful for particular reasons.

Furthermore, the references cited by the Examiner regarding characterization of proteins of other retroviruses do not establish lack of utility for the claimed polypeptides. In fact, these references indicate *well-established* utilities for the claimed polypeptides. A well-established utility is a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one of skill in the art. MPEP 2107.02.II.B. The claimed polypeptides are products of a mammalian retrovirus. It is acknowledged in the Office Action that "SEQ ID NO:3 encodes at least 3 different proteins, gag, pol, and env" (page 3). The polypeptide components of retroviruses have a number of conserved, well-known functions. As noted in Freed (*Virology*, 251:1-15, 1998), "[t]he Gag proteins of HIV-1, *like those of other retroviruses*, are necessary and sufficient for the assembly of virus-like particles" (abstract, first sentence, emphasis added). Products of the pol region encodes reverse transcriptase and integrase enzymes (See, e.g., Coffin, *Fund. Virol.*, Ch. 27, page 654, 1991, copy enclosed herewith as Exhibit A). Env gene products are expressed on the surface of virions and mediate interactions with cell-surface receptors (Coffin, *Fund. Virol.*, Ch. 27, page 654, 1991). Certain functions of retroviral polypeptides are well known to those of skill in the art.

The Office Action cited lack of details regarding proteolysis of the claimed polypeptides as evidence of lack of utility. The relevance of this to the well-established and asserted utilities is not understood. Freed, cited in the Office Action, says that "[e]xpression of retroviral Gag precursor proteins is both necessary and sufficient for the assembly and release of noninfectious, virus-like particles; Gag processing by [viral protease] is *not required* for particle production" (*J. Virol.*, 76(10):4679-4687, 2002, at page 4679, left col., second paragraph, emphasis added). Thus, proteolysis is not required for some functions of retroviral proteins.

Regarding Applicant's discussion of asserted utilities in the prior Amendment in Reply, filed September 1, 2006, the Office Action stated that

> [t]his argument is not persuasive because this is a "reach through" utility, that is, one must make all of the polypeptides encoded by SEQ ID NO:3, make all of the antibodies specific to these polypeptides, then determine for themselves if the detection of these polypeptides has any bearing on xenograft transfer. It is not for another to arrive at Applicant's invention. As noted, many polypeptides are encoded by SEQ ID NO:3. Applicants have not provided a function for any of these polypeptides…One cannot know until they determine for themselves if detection of any one of the polypeptides will be an indication that a donor animal will pass the nucleic acid retroviral vector to the xenograft recipient and cause deleterious effects. Thus, the polypeptides encoded by SEQ ID NO:3 lack a specific utility (page 5).

This is respectfully traversed. The asserted utilities are not "reach through" utilities. Applicant has asserted that the claimed polypeptides are useful, e.g., in methods of detecting retroviruses for screening animals and organs for transplantation. The Office Action cites no factual basis for concluding that one needs to "make all of the polypeptides encoded by SEQ ID NO:3… then determine for themselves if the detection of these polypeptides has any bearing on xenograft transfer" in order to practice the asserted utilities. The asserted utilities are not ones that require further research to identify or reasonably confirm. One of skill in the art possesses the technical capabilities to produce and use the claimed polypeptides. Applicant has explained that swine are a potential source of organs for xenotransplantation (specification, page 1, lines 16-17). Detection and analysis of swine viruses is important for recognizing infection in swine and managing infection in xenotransplantation.

Applicant notes that an assertion of utility is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. MPEP 2107.2.III.B. The Office Action suggests that the utilities lack credibility where it states that "[o]ne cannot know until they determine for themselves if detection of any one of the polypeptides" will be an indication that a donor animal will transmit a retrovirus and cause deleterious effects. If this rejection is maintained, Applicant requests clarification as to what is meant by this statement. Is it doubted whether positive detection of a retrovirus protein correlates with virus transmission? In the prior Amendment in Reply, Applicant cited evidence that swine retroviruses infect human cells. Is it doubted whether transmission of a retrovirus causes disease? Given the knowledge of the involvement of retroviruses in disease, not to mention the desire to avoid unnecessary exposure to pathogens, particularly in immunocompromised transplant recipients, the logical basis for screening animals and tissues to avoid retrovirus transmission is neither "seriously flawed" nor based on inconsistent facts. In view of the foregoing, Applicant requests withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1(c), 6, 8 (g-i), 15-17, 18(c), 23, and 26(c) were rejected as lacking written description. According to the Office Action,

> [t]he specification and claims do not set forth any structure of or function for the claimed polypeptides encoded by SEQ ID NO:3, having at least 85% identity to SEQ ID NO:3, or having at least 30 or 100 nucleotides from SEQ ID NO:3. Also, this polypeptide is not in hand. (Office Action, page 6).

This rejection is respectfully traversed. The claims are directed to polypeptides encoded by SEQ ID NO:3, polypeptides encoded by nucleic acid molecules that have a high degree of identity to SEQ ID NO:3, polypeptides encoded by nucleic acid molecules that hybridize under high stringency conditions to a molecule consisting of the fully complementary sequence of SEQ ID NO:3.

The specification discloses SEQ ID NO:3 and polypeptides encoded by SEQ ID NO:3. See Figure 3. The statement that the specification does not set forth "any" structure for the claimed polypeptides is incorrect. The specification provides complete structure for

polypeptides that fall within the claims. For example, the specification discloses the complete amino acid sequence of polypeptides encoded by nucleotides 585-2156 of SEQ ID NO:3, nucleotides 2307-5741 of SEQ ID NO:3, and nucleotides 5620-7533 of SEQ ID NO:3. See Figure 3. The genera of polypeptides encompassed by the claims are related by a high degree of identity to polypeptides encoded by SEQ ID NO:3. Possession of a claimed invention can be shown in a number of ways. Recitation of structure is one of ways to demonstrate possession. The correlation of structure with function can be used to support written description when minimal structure is disclosed. In the present case, far more than minimal structure is disclosed. The claims are limited to polypeptides encoded by sequences related by a high degree of identity to SEQ ID NO:3. The structural disclosure satisfies the written description requirement.

Applicant maintains that one of skill in the art is able to identify polypeptide sequences encoded by a given nucleotide sequence. The Examiner rejected this argument because "there is no correlation of structure with function" (Office Action, page 6). One need not know the function of a polypeptide *a priori* to be able to identify an open reading frame in a nucleotide sequence. It is noted that claim 1, as amended, and claim 8, refer to the specific region(s) of SEQ ID NO:3 that encode(s) the polypeptide.

Applicant requests withdrawal of the rejection of claims 1(c), 6, 8 (g-i), 15-17, 18(c), and 26(c) as allegedly lacking written description.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1(c), 6, 8 (g-i), 15-17, 18(c), 23, and 26(c) were rejected as indefinite for referring to "a polypeptide." The Office Action stated that "retroviruses encode many polypeptides; therefore it is not clear which polypeptide is being claimed" (page 6).

This rejection is traversed. Claims 1, 8, 18, and 26 are genus claims, i.e., they encompass multiple species.[1] Genus claims are acceptable ways to claim one's invention. MPEP 2173.05(h).

[1] Claims 6 and 23 have been canceled.

Claim 1 was rejected for reciting "85% identical." The Office Action stated that "'identical' is an absolute term, meaning that one thing is identical to another or it is not. Thus, one skilled in the art cannot know what a fraction of identical means" (page 7).

This is traversed. The meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. The meaning of a term in the claims may be evidenced by the specification. The term "identical," in the context of nucleotide and amino acid relatedness, has an art-recognized meaning, which is also set forth in the specification at page 25, lines 23-33. It is indeed possible for polymeric macromolecules to be identical at some positions and mismatched at others when the sequences of the macromolecules are aligned. The interpretation of "identical" as a purely absolute term is inconsistent with its usage in the art and the specification. Despite the Examiner's interpretation of "identical" as an absolute term, percent identity was used by those of skill in the art at the time the application was filed to describe the degree of relatedness of sequences. Two abstracts that use this terminology are enclosed. These published in 1986 and 1990. Both refer to percent identity to describe relatedness of polypeptide and nucleotide sequences.

Claim 18 was rejected for reciting "70% homology." The Office Action stated that "'homology' is a qualitative term and not a quantitative term. Thus, one skilled in the art cannot know what 70% homology means" (page 7).

This is traversed. "Homologous," in the context of nucleotide and amino acid relatedness, is expressly defined in the specification at page 25, lines 23-33. Understood in light of the knowledge of one of skill in the art and the definition in the specification, the term "homology" is clear.

Claim 18 was also rejected for using the term "corresponding." According to the Office Action, "it is not clear what a corresponding human, mouse, or primate retrovirus sequence is, or the last five 3' bases may be" (page 7).

This is traversed. Applicant request that the Examiner consider the point made previously in the Amendment in Reply filed September 1, 2006. Retroviruses have a common genomic structural organization. A region is corresponding if it is at the same relative position.

One of skill in the art can compare a sequence from one region of a swine retrovirus to a sequence in a region at the same relative position in a human, mouse, or primate retrovirus. For example, a sequence at the 5' end of a gag gene of a swine retrovirus can be compared to a sequence at the 5' end of a gag gene of a human retrovirus.

Claim 18 uses the phrase, "wherein the last five 3' nucleotides are unique to the selected sequence." This phrase is also clear to one of skill in the art. It simply refers to the five nucleotides at the 3' end of the sequence of SEQ ID NO:3 encoding the polypeptide. To satisfy the limitation, the last five base pairs of the sequence from SEQ ID NO:3 must be unique, i.e., the base pairs are not identical to the base pairs in the corresponding human, mouse, or primate retroviral sequence.

Claim 18 was rejected for lacking "(c)" preceding a limitation in the claim. This rejection is moot in view of the amendment to the claim to remove lettered subheadings.

Non-elected inventions have been canceled from the claims under examination.

In view of the foregoing, Applicant requests withdrawal of the rejections of the claims under 35 U.S.C. § 112, second paragraph.

Objection to the Specification

The specification was objected to for failing to include the polypeptide sequences depicted in the drawings in the Sequence Listing. A substitute Sequence Listing is being filed herewith which includes the polypeptide sequences.

A Notice of Appeal and Petition for Extension of Time are being filed herewith. Enclosed is a check for the Petition for Extension of Time fee. Please apply the $1020 extension fee, the $500 notice of appeal fee, and any other charges or credits to deposit account 06-1050, referencing attorney docket no. 14846-011004.

Respectfully submitted,

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